Summary of Teleconference on the Vaccine Vial ID Initiative Held on September 19, 1997

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The CDC is spearheading an effort to improve the transfer of vaccine identifying information from the vaccine vial to medical records. The CDC's two major systems for monitoring vaccine safety, the passive Vaccine Adverse Event Reporting System (VAERS) and active prospective Vaccine Safety Datalink (VSD), face significant error and vagueness rates in determining exactly which vaccine, from which manufacturer, and the lot number, a child actually received. This problem also affects the accuracy and usefulness of immunization registries and the important functions they serve. This problem may be exacerbated as the new vaccines, including combination vaccines are recommended for use and become available.

This issue has been presented at the last two Advisory Committee on Immunization Practices (ACIP) in the context of draft guidelines for combination vaccines. The CDC would like manufacturers to develop unique vaccine identifier information suitable for both manual and automated immunization record systems. The CDC's suggestions include standardization and simplification of lot numbers and/or standardized peel-off identification stickers to accurately transfer the required information from the vaccine vial or syringe to the patient's medical record. Translations of the textual information on the stickers into machine-readable bar codes, following Uniform Code Council (UCC) standards, might facilitate accurate electronic transfer of the information into immunization registries.

To begin the Vaccine ID Initiative process , the CDC convened a conference Friday, September 19th (10AM-12PM PDT) to discuss the possibility of a pre-ACIP meeting October 21st in Atlanta, and what the agenda would entail. Representatives from the vaccine industry (manufacturers), the FDA and the CDC participated in the conference call. It was decided to have the meeting (tentatively scheduled the afternoon of October 21st, at Corporate Square in Atlanta). Dr. Joshua Schwartz at the CDC is writing a background paper which he will send out soon, and then a draft agenda will be circulated for comment.

Participants in the September 19th phone conference were as follows:

Kathleen Maher, Merck Marketing, filling in for Tom Vernon
Chris Grant, PMC, Government Policy
Ron Filipski, PMC, Director of Filling, Packaging, Warehousing and Distribution (he is also heading up their Bar Code Initiative)

Denny Foley, Wyeth-Lederle, Global Regulatory Affairs
John Kropos, Wyeth-Lederle, Packaging
Carolyn Hardegree, CBER, FDA
Bob Chen, CDC, National Immunization Program (NIP), VAERS and VSD
Bruce Weniger, CDC, NIP
Susan Abernathy, CDC, Data Management Division, involved in registries and electronic data transmission, US rep. to Internat.Standards Organization.
Joshua Schwartz, CDC, NIP, Oakridge Fellow, dedicated to this Initiative
Steve Sepe, National Vaccine Program Office, Vaccine Safety and Adult Immunization Task Forces
Lizzie Leininger, Chiron, Regulatory Affairs
Yvonne McHugh, Chiron, Scientific Affairs

Synopsis

The meeting on Oct.21st will provide an opportunity to have presentations by Bar Coding organizations, the CDC's work on standards for bar coding records, the FDA viewpoint (they haven't regulated this to date and each manufacturer has its own way of assigning lot numbers, etc.), and the manufacturers' perspective as well as how they currently assign lot numbers (this is voluntary). The goal is to identify the problems, hurdles, potential solutions and get a consensus on how to move forward.

C. Hardegree said that the FDA will be very interested in seeing what is proposed in this Initiative. She commented that the manufacturers should talk within their organizations to see how this would affect their other manufactured products.

Ron Filipski (PMC) summarized the overall purpose of the Oct.21st meeting: define what we need to do, how we need to accomplish it and what questions are to be addressed, e.g., a universal way of coding, universal placement of the information (equipment regulated); technical issues with multidose containers, whether peel-off labels would constitute a permanent record (HCFA, HRSA), and so on. It was stressed by the CDC that a lot more than safety databases and registries are involved here: HMOs are very interested, e.g., inventory and billing.

So far, Susan Abernathy's group has devised a scheme to code vaccines on the market. An ANSI standard for "vaccine codes" was sent out early this year. They want this to be an international effort so that numerous interfaces don't have to be built (think globally). An example of the ANSI code for a vaccine is: [MSD(company)##(vaccine, e.g., Hib broken out into several "types" e.g, number of doses) Year, Lot#, expiration date. ANSI is made up of 1600 vendors and international organizations, and includes

representation from Canada, Finland, Germany, Japan (and US). The NDC (National Drug Code) number would be part of this system, too.

Lizzie Leininger commented, and it was acknowledged by the CDC, that the error rate may be in large part not how the labels are coded, but that medical records and record-keeping aren't harmonized and simplified . This is a major loophole. Bob Chen reported that 2% of children in the US are in the west coast HMOs where the Vaccine Safety Data link (formerly the Large Linked Data Base) is in place, and a survey found an error rate of 17% in manual recording of lot numbers, e.g., numbers were transposed. There are similar problems with the VAERS. It may be that standardizing records should be included in the scope of this Initiative

Problematic labeling was mentioned, such as "impressed" printing of numbers into the product box without ink, hard to read; Hib/DPT/diluent with one lot number on the outer box and separate and different lot numbers on each vial.

Bob Chen said that the lot number sequence has meaning internally for the companies but to an outsider, it is not clear. Can this be standardized? The manufacturers thought this was very unlikely (and a discussion subsequent to the 9/19/97 meeting confirmed that).

Chris Grant (PMC) asked the CDC to prepare a visual schema with the ultimate flow of the information recorded, that is: 1) coded information; 2) transfer of information from the product to the record; 3) the information is pulled into systems for recording adverse events and ultimately into immunization registries and so forth.

Bob Chen said he will clarify which errors are being made in the VSD and VAERS and present this. This will be of great interest to all.

Conclusions and Action Items

The purpose of the Vaccine ID Initiative is: 1) to increase the accuracy, efficiency, compatibility and of transfer of information from product to the record, and the data capture; 2) to create a system that is manually and electronically compatible.

Invited will be representatives of the vaccine industry, bar coding industry, label vendors, FDA, CDC, AAP, AKC (All Kids Count), clinical practice/providers.

Ron Filipski (PMC) agreed to present (30 min.) the industry view at this meeting, and the manufacturers have been asked to work with him to present our concerns and comments, and perhaps examples of our current labels. A conference call was planned for Friday Sept.26th at 8AM EDT. On October 21st, Ron Filipski will present the: 1) technical issues, current processes, potential barriers and anything we're currently doing that is synergistic with the Vaccine ID Initiative goals. (Bob Chen also asked if the manufacturers' would be willing to explain how they assign their lot numbers and no one voiced an objection).

Susan Abernathy will present the existing standards, i.e., CPT, HL7, NDC and the UCC, and the extent to which they can be adapted to the goals of this Initiative. She is proposing up to 20 alphanumeric digits for the lot number, 6 digits for the expiration date, NDC#, etc.

Draft Agenda:

- Introduction
- Goals - accuracy, efficiency, convenience, manual/electronic systems
- Describe problem - CDC VAERS
- When errors occur in the information flow
- Ron F. et al./vaccine industry (current processes and potential barriers)
- Existing Standards Groups (ANSI, NDC, CPT, UUC)
- Clinical Practice Groups (Maryland Acad.Ped., AAP, AKC)
- FDA?
- Potential solutions

The meeting on Oct.21st in Atlanta will probably start at noon and run for several hours. The ACIP will take place on Oct. 22 and 23rd .